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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,834	01/30/2006	Hisashi Narimatsu	159-89	5006

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EXAMINER	
RAGHU, GANAPATHIRAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,834	NARIMATSU ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1-5 and 17-22, drawn to nucleic acid with SEQ ID NO: 1 or a complementary nucleotide sequence thereof, encoding a β1,3-N-acetyl-D-glucosaminyltransferase, probes or primers, vectors, host cells and the method of making the said polypeptide.

Group II: Claims 6-8 and 12, drawn to a method of testing canceration of a biological sample, comprising using a nucleic acid probe or primer of group I to measure the transcriptional level in a biological sample.

Group III: Claims 9-11, drawn to a method of examining the effectiveness of treatment for cancer therapy, comprising using a nucleic acid probe or primer of group I to measure the transcriptional level in a biological sample before and after treatment.

Group IV: Claims 13-16, drawn to a polypeptide β1,3-N-acetyl-D-glucosaminyltransferase having an activity of transferring N-acetyl-D-glucosamine from a donor substrate to an acceptor substrate through β1,3-linkage, wherein the glycosyltransferase has any one of the following sequences with SEQ ID NOs: 2, 16 or 17, wherein one or several amino acids are substituted, deleted or inserted or an amino acid sequence with at least 40% identity to sequences with SEQ ID NOs: 2, 16 or 17.

Group V: Claim 23, drawn to an antibody, which binds specifically to the elected polypeptide of group IV.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following categories:

1) A product and a process specially adapted for the manufacture of said product or

2) A product and process of use of said product; or

3) A product, a process specially adapted for the manufacture of said product and a use of said product; or

4) A process and an apparatus or means specifically adapted for carrying out the said process; or

5) A product, a process specially adapted for the manufacture of said product and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states: If an application contains more or less than one of the combination of categories of in an invention set forth in paragraph (b) of this section, unity of invention might not be present.

37 CFR 1.475 (d) also states: If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) 1.47(c).

37 CFR 1.475(e) further states; the determination whether a group of invention is so linked as to form a single inventive concept shall be without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

In the instant application the products of groups IV and V differ substantially from one another to the extent that they have a different structure and function. The polypeptides of group IV have catalytic activities, whereas the antibody of group V are mainly used for binding to the polypeptides of group IV, lack catalytic/enzymatic activity. The two products can be used exclusive of each other such that they do not share unity of invention under 37 CFR 1.475.

Furthermore, the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they also lack the same or corresponding special technical features for the following reasons:

The technical features linking the inventions of Group I-V appears to be that they all relate to β1,3-N-acetyl-D-glucosaminyltransferase and the method of making and using the said enzymes and also relates to nucleic acid, the nucleic acid for testing canceration, and a method of testing the canceration of a biological sample based on a difference in the expression level of the nucleic acid in the biological sample; as well as, to a glycosyltransferase and a nucleic acid encoding the glycosyltransferase.

Vavasseur et al., (Glycobiolgy, 1995, Vol. 5 (3): 351-357), disclose the isolation of β1,3-N-acetyl-D-glucosaminyltransferase and characterization of said enzyme activity from normal colonic mucosal tissues and lack of activity in human cancer cell line. The examiner takes the position that since said reference discloses the level of expression of the protein i.e., the transcriptional level of the gene in normal and cancerous tissues and hence the technical features linking the inventions of Group I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121 and 372. Therefore, election is required of one of inventions I-V and one of inventions (A)-(C).

(A). the amino acid of SEQ ID No: 2.

(B). the amino acid of SEQ ID No: 16.

(C). the amino acid of SEQ ID No: 17.

The various sequences of Groups A-C have different structure and encode different polypeptides.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single appropriate disclosed species i.e., a single SEQ ID NO: associated with the respective group for prosecution on the merits to which the claims are restricted. Note that this is a restriction requirement to sequence and NOT a species election.

MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141et seq. It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Examination will be restricted to only the elected group and the elected amino acid /nucleotide sequence.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

May 22, 2006.

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1652